

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

TERESA L. STEVENS,  
Plaintiff

v.

CNIL ACTION NO. 2:16-cv-0265

BOSTON SCIENTIFIC CORPORATION, EMAI  
PLASTIC RAW MATERIAL CO, LTD.,  
PROXY BIOMEDICAL LIMITED, AND  
LUXILON INDUSTRIES NV,  
Defendants.

MEMORANDUM IN SUPPORT OF PLAINTIFF'S SEALED, AMENDED MOTION TO  
REMOVE "CONFIDENTIAL" DESIGNATION FROM DOCUMENTS

Plaintiff Teresa L. Stevens, submits this Memorandum In Support of Plaintiff s Amended Motion to Remove Any "Confidential" Designation From Documents submitted with Plaintiff s Original Complaint and Motion for a Temporary Restraining Order and a Preliminary Injunction, as well as all documents regarding the alleged Marlex BSC obtained from China.

I. INTRODUCTION

Plaintiff, Teresa Stevens, previously filed her Motion to Remove Confidential Designation from Documents [ECF Dkt. 11], asking this Court to de-designate all of Boston Scientific's ("BSC") improperly stamped "confidential" documents supporting Plaintiff s Original Complaint and Motion for a Temporary Restraining Order and a Preliminary Injunction. These documents, and all other documents regarding the alleged Marlex obtained from China, were produced pursuant to a Stipulated Protective Order, Pretrial Order # 11 in MDL No. 2326 ("PTO #11"), which permits parties to designate materials produced as "confidential" or "highly confidential." PTO #11 is the kind of protective order that has become increasingly common in complex litigation that allows parties to unilaterally designate materials as confidential without

any showing of good cause; any materials so designated are protected until the designation is withdrawn or the Court rules otherwise. A party's right to designate materials as "confidential" is not, however, unfettered. As specifically set out in ¶ II.B.2. of PTO #11, a party is only permitted to designate materials as "confidential" if it has a good-faith belief that the material qualifies for protection under Rule 26(c).

Despite the "good-faith belief" requirement, Boston Scientific Corporation (BSC) abused PTO #11. In fact, despite having produced approximately 600,000 pages of documents, BSC apparently stamped the vast majority of those documents as "confidential"—many, many that are plainly not so. If there are many documents in the 600,000 or so pages BSC produced that were not stamped "confidential," Plaintiff has not seen them. BSC used the "confidential" designation without even the slightest consideration of whether it had any good-faith basis to believe the documents qualified for the "confidential" designation. Worse, BSC used this blanket "confidential" designation to conceal from the public the fact that, starting in late 2012 or early 2013, all of its mesh products came from counterfeit mesh bought in China without any original source documentation. Worse, BSC is still using this Chinese mesh today—implanting over 55,000 women a year with this Chinese, counterfeit, unlawfully smuggled mesh.

The matter came to a head when Plaintiff discovered in some of those "confidential" documents that BSC obtained degraded and counterfeit material for use in its mesh products that likely pose an even greater risk than the products that landed BSC in this MDL in the first place. The details are set out in Plaintiff's Motion for a Temporary Restraining Order and a Preliminary Injunction, and Plaintiff's Original Complaint. Although the documents showing BSC's misconduct do not remotely qualify for the "confidential" designation, under the terms of PTO #11, Plaintiff cannot "distribute, transmit, or otherwise divulge" material marked "confidential,"

and unless the designation is removed, at the close of this litigation Plaintiff would be required to destroy the evidence. No one outside this litigation would ever know, and BSC could continue its business as usual.

Prior to filing her Motion, time and again, Plaintiff's counsel presented BSC with requests, consistent with PTO #11, that BSC remove the improper designations. BSC refused. BSC's counsel made clear it was not going to re-visit any of its wholesale "confidential" designations, and took the reverse position it was Plaintiff's burden to go through millions of BSC documents—all stamped "confidential" in wholesale fashion—and ask for de-designations, or "downgrades." None of this is in the stipulated protective order BSC agreed to follow. None of this is in the Federal Rules of Civil Procedure BSC must follow. And none of this is appropriate. Plaintiff submits that BSC's intentional concealment of these critical documents, in bad-faith violation of PTO #11, places her and tens of thousands of other women at imminent risk to their health and safety.

Under **if** II.B.4. of PTO #11, any party may at any time challenge the redaction or designation of information as "confidential" by providing written notice to the designating party, and if after a meet-and-confer, the parties are unable to reach an agreement, apply for an appropriate ruling from the Court. Plaintiff provided the required written notice (through a series of emails and phone calls to BSC's counsel) and met and conferred, but did not reach an agreement. Plaintiff therefore now asks the Court to intervene, and to strip the materials produced by BSC of the "confidential" or "highly confidential" designation.

## II. STATEMENT OF FACTS

### A. **The Stipulated Protective Order**

Prior to the Plaintiff's case being filed, the Honorable Jude Goodwin presiding over MDL No. 2326 entered a Stipulated Protective Order, or PTO #11. PTO #11 permits counsel to

designate as "confidential" "any material the producing party believes in good faith constitutes or disclosed information that qualifies for protection pursuant to Fed. R. Civ. P. 26(c), specifically information that is trade secret or other confidential research, development, or commercial information, and materials that are deemed confidential under Federal Drug Administration ("FDA") regulations and Health Insurance Portability and Accountability Act ("HIPPA") statutes and/or regulations." PTO #11, if II.B.2. Such a designation may, however, be challenged "by any party at any time," and "the party claiming the designation of confidentiality or redaction has the burden of establishing that the confidential designation or redaction is proper." PTO #11, if II.B.4. Finally, the Order provides: "Nothing in this Order shall prevent any other party from seeking amendments broadening or restricting the rights of access to or the use of **CONFIDENTIAL** and/or **HIGHLY CONFIDENTIAL** material or otherwise modifying this Order...." PTO #11, **if** II.C.4.

**B. BSC's Blanket Designation of Confidentiality**

BSC literally gave no consideration to whether documents it designated as "confidential" qualified for that classification. In fact, it appears that the "confidential" designation is just a part of BSC's Bates routine stamping procedure.

BSC was originally sued in the transvaginal mesh litigation in Massachusetts state court. BSC produced a so-called "Core Set" of documents in Massachusetts. BSC then produced this Core Set of documents in Southern District of West Virginia MDL 2326, not in response to any particular document request. The BSC response includes pages of generic objections and then a broad statement that the Core Set is being produced subject to the boilerplate objections. Simply put, BSC never responded to specific production requests, and never updated this "Core Set's" document redactions, privilege claims, or other matters. So, the undersigned began a meet-and-confer process with BSC about these deficiencies, and continued reviewing thousands of

documents produced without any connection to a specific production request. It was a daunting, expensive, and time-consuming task-precisely what BSC designed it to be.

Upon review, Plaintiff determined that Defendant's conduct with regard to redactions and confidential designations in this matter have been similarly abusive. BSC's original privilege log contained only 800 entries, which left nearly 8,000 redactions within the Core Set that were not logged. Once challenged by Plaintiff's current counsel, BSC has now agreed to remove redactions on over 5,000 improperly redacted documents which were never logged, in violation of the Court's order. There's more.

BSC abused the agreement stipulated in PTO #11 which allows BSC to produce documents marked as "confidential" if the producing party believes in good faith constitutes or discloses information that qualifies for protection pursuant to Fed. R. Civ. P. 26(c), specifically information that is trade secret or other confidential research, development, or commercial information and the materials that are deemed confidential under Federal Drug Administration ("FDA") regulations and Health Insurance Portability and Accountability Act ("HIPAA") statutes and/or regulations. Marking a document "confidential" label restricts the use of the documents. **The vast majority of the documents in the Core Set are produced subject to the boiler-plate objections and marked "confidential" under the protective order.**

BSC's nearly wholesale designation of the Core Set documents as Confidential violates PTO # 11. There are countless documents that BSC marked as confidential with no good-faith basis. BSC's rampant over-designation as "confidential" virtually all these documents caused significant problems to the Plaintiff and her counsel, not to mention concealed from thousands of women the true nature of the mesh being implanted inside them. BSC agreed to PTO #11 that required BSC to exercise good faith in designating information as confidential-

not wholesale stamping designed to protect BSC's stock-market price from the news it's all built atop a counterfeit resin smuggled out of China.

Plaintiff challenged these designations through numerous email meet-and-confers and phone calls. In December 2015, Defendant BSC "downgraded" several documents, meaning it removed the confidentiality of the documents, and therefore, the removed the restricted use of the documents. However, many of the documents Plaintiff intends to rely on, and many documents that affect public health and safety were not downgraded, and the use of these documents is still restricted. Plaintiff requests the Court remove the confidential designation from all documents regarding the alleged Marlex BSC obtained from China, including, but not limited to, those documents submitted with Plaintiff's Original Complaint and Motion for a Temporary Restraining Order and a Preliminary Injunction and attached to this motion.

**C. Facts Supporting the Procurement, Smuggling, and Use of Counterfeit Resin from China**

Below are facts taken from internal documents and emails produced by BSC which support the need for public use of the documents to protect public health and safety:

- 2005: Phillips Sumika terminated BSC contract for Marlex HGX-030-01 for use in permanent implant device.
- Ex. 1 - BSCM13000000033
- 2008: Per BSC presentation, Philips Sumika confirmed product line discontinued in 2008 timeframe and declines request for special BSC run due to issues with the reactor.
- Ex. 1 - BSCM13000000033
  - Ex. 2 - BSCM13800009806 – H. Batz says Phillips obsoleted the material in 2005 (previously Ex.19)
- 12/6/10: BSC used around 1,200lbs of Marlex resin per year.
- Ex. 2A - BSCM13800009673
- 5/2011: BSC had a previous, painful experience with smuggling balloons out of China.
- Ex. 3 - BSCM04400011225
  - Ex. 4 - BSCM06701716235 -previous experience was painful

- 7/19/11: BSC had an urgent need for Marlex and needed the material right away.
- Ex. 2 at BSCM13800009806 - critical issue with Marlborough division
  - Ex. 5 BSCM06700722854 – "fire drill" due to impending shortage of Marlex
  - Ex. 6 at BSCM11200014918 – \$120,000,000 impact to the business without Marlex.
- 7/19/11: Zhao looked up Marlex product on alibaba.com (known counterfeit website).
- Ex. 2 at BSCM13800009803
  - Ex. 7 - BSCM13800008924 – Zhao states he visited all 5 distributors found from alibaba.com
  - Ex. 7A - Google result page for search of alibaba.com
- 7/19/11: All Chinese sources for Marlex were located in Donggaun, in Guangdong province, China – a region known for counterfeit products.
- Ex. 2 at BSCM13800009803
  - Ex. 8 - [www.chinadaily.com.cn/china/2014-07/30/content\\_18217996.htm](http://www.chinadaily.com.cn/china/2014-07/30/content_18217996.htm)
  - Ex. 8A - <http://appvl.linktv.org/videos/genuine-pride-for-knockoff-goods-in-guangzhou>
- 7/20/11: H. Batz advised Zhao not to tell the Chinese distributors where the Marlex will be used because it might scare them away.
- Ex. 2 at BSCM13800009802
- 7/21/11: Mitch Wheeler (at BSC) asked Charlie Smith whether there was any way to test the resin to ensure it is not counterfeit or contaminated, noting that sourcing from China is risky.
- Ex. 9 - BSCM13800009259
- 7/21/11: BSC (Ann Charest) needed the following from Luxilon: (1) picture of material packaging, (2) Copy of CoC, (3) MSDS, (4) Picture of actual resin if possible, and (5) other requirements BSC would insist on from the distributor.
- Ex. 2 at BSCM13800009800
- 7/25/11: Zhao stated that Distributor 1 (EMAI) sold their inventory to another distributor last week, but will have more in tomorrow – the distributor will not know exactly what is in the shipment until the shipment reaches customs in Guangzhou.
- Ex. 7 at BSCM13800008924
- 7/27/11: Peter Horton requested Pinnacle Lite U.S. new sales forecast numbers to calculate current Marlex inventory run out dates.
- Ex. 10 - BSCM06100029374
- 7/28/11: BSC really needed a C of C. McCaslin knew, but asked if there is no C of C if the deal would be dead. McCaslin then said he wondered if he could get the lot number from the bag and contact Phillips.
- Ex. 10A – 79 0001

7/29/11: In response to an inquiry on how much Marlex resin was on hand by location, Dean King (at Proxy) responded that there is only 700 pounds of resin was on hand at Luxilon (Belgium).

- Ex. 11 - BSCM13800009697
- Ex. 1 – Lessons learned: Increased vigilance required in monitoring consumption of last-time buy volumes.

7/2011- 8/2011: (prior to 8/2/11 email) – Mccaslin reached out to Bob Rhoades – a manager from Phillips. They discussed Phillips would not provide assistance with additional resin supply. Rhoades stated Phillips was not willing to sell Marlex to BSC.

- Ex. 12 - Mccaslin Depo -pages 48 - 53

8/4/11 Mike Kelly, BSC Vice President of Operations, emailed H. Batz (BSC) stating that business revenue of \$120,000,000 will be impacted without the Marlex.

- Ex. 6 at BSCM11200014918

8/5/11 Mccaslin told group (including Pedersen, printed by Pedersen with handwriting) that Phillips will not do business with BSC at any price

- Ex. 13 - BSCM06701713768

8/5/11 Mccaslin told group (including Pedersen who prints the email with handwriting) that a distributor without COC is high risk.

- Ex. 13 - BSCM06701713768

8/12/11 Zhao shipped out 1 bag to U.S. from 1 of the 5 possible distributors (not EMAI) Zhao found on alibaba.com. Charlie Smith (BSC) received this bag from Zhao on 8/19/11 and the product is obviously fake and the resin is counterfeit.

- Ex. 14 - Shipping email -no bates 72\_0001
- Ex. 15 - Receipt email- BSCM12900000088

8/15/11: Mccaslin (BSC) asked Zhao for the lot numbers that are in the 2 tons. Zhao sent Mccaslin a picture, and Mccaslin noted "very nice work!" Zhao responds that all 17 tons (34,000lbs) are from the same lot number.

- Ex. 16 - BSCM06701715875

8/15/11: Ann Charest (BSC) reached out to 3rd party (AK Plastics) and asks AK to use their connections at Phillips to obtain a copy of the C of C for BSC.

- Ex. 19 at 13500000015

8/15/11: Mccaslin asked Zhao to push a bit on getting the C of A – stated it would be a big help.

- Ex. 15 at BSCM12900000089
- Ex. 16A at BSCM11500006823
- Ex. 16B – sample C of A - BSCI1800027286

- 8/21/11: 1st Shipment: 4,000lbs of EMAI resin shipped from Hong Kong to Marlborough, MA
- Ex. 15 at BSCM12900000086
  - Smuggled out of China using over-bag. Shipper put a blank bag over the original bag so it was not inspected. Ex. 15 at BSCM12900000074
  - 12/1/11 – Zhao says BSC took a chance with the first 4,000 pounds. It was a small amount, by air, so overall less chance for audit and the shipper who handled it was not "over-cautious." Ex. 17 - BSCM11500006697
- 8/25/11: 3rd party (AK Plastics) confirmed to BSC that the lot number from the bags being obtained from China is not in the Phillips database and "may be a number that was made up by the person that packed the material."
- Ex. 19 at BSCM13500000012
- 8/26/11: First 4,000lbs of resin arrived in Marlborough, MA. 2 bags broke and were scrapped.
- Ex. 18 - BSMC07700277053
- 8/30/11: Smith asked Zhao to confirm that the 15 tons is the same lot number as the 4 tons received on 8/26/11. Zhao responded that the 15 tons is from the same lot, based on the assurances of the distributor, EMAL Zhao stated he thinks BSC can trust the distributor based on what he had provided BSC thus far.
- Ex. 15 at BSCM1290000085
- 8/30/11: BSC has already paid 40% deposit on another 30,000lbs of resin firm EMAL EMAI will hold it for 2 months while testing is completed.
- Ex. 15 at BSCM12900000086
- 8/31/11: 3rd party (AK plastics) contacted Phillips and confirms that the lot number on the bag in the picture sent by Zhao is not a lot number in Phillips system.
- Ex. 19 - BSCM13500000010
- 9/16/11: Pinnacle Lite Pelvic Floor Repairs Kits received FDA clearance and a decision is necessary on whether Pinnacle Lite will use Marlex resin, as this will significantly impact run out date for current Marlex inventory.
- Ex. 20 - BSCM06100027516
  - The current Marlex use of 1,200lbs per year (Ex. 2A – BSCM13800009673) did not include any U.S. sales for Pinnacle LITE. Ex. 20 - BSCM06100027516
- 10/10/11: Production run at Luxilon (Belgium) using EMAI resin.
- Ex. 21 at BSCM04200117214
- 10/13/11: Luxilon informed Dean King at Proxy (who forwards the email to Charles Smith) that filament breaks at spinneret when using the Chinese resin.
- Ex. 22 - BSCM07700280496

- 10/13/11: Cambridge Polymer Group test results noted a difference in the resin tested and additional testing is necessary. Ex. 33
- 11/9/11: Final payment made to EMAI to purchase remaining 30,000lbs of resin.
- Ex. 23 at BSCMI 1500007222
- 11/14/11 Only 3,000 pounds of resin left in Marlborough, and 165 pounds left at Luxilon (Belgium)
- Ex.23 -BSCMI1500007219
- 11/21/11 BSC confirmed there was no CoC or CoA for the EMAI resin.
- 11/21/11 - Zhao says all of the original paperwork is lost. Ex. 16 - BSCM12900000074
  - 12/18/11 - Ann Charest (BSC) says original paperwork was lost/forgotten. Ex. 24 -BSCM13500000971
- 11/21/11 Zhao suggested that he ship 10 tons to the U.S. split into 2 small containers and have 5 tons in each, in case of any accident, like falling over sea, etc.
- Ex. 15 at BSCM12900000074
- 11/22/11 Vialle told Zhao that he doesn't want any problems with Chinese because previous experience was painful
- Ex. 4 - BSCM06701716235
  - For previous experience, *see* May 2011 entry - Ex. 3 - BSCM04400011225
- 11/20/11: George Vialle (BSC) asked if anyone is aware of a method to deal with export of undocumented, imported goods from China. He asks whether there is an expert they can consult.
- Ex. 16A at BSCMI 1500006807
- 12/20/12: EMAI moved 30,000lbs into a different, long-term storage facility that is safer, better controlled and could be long-term storage.
- Ex. 25 - BSCMI 1500006879-80
- 2/21/12 Zhao told Charlie Smith the chance of being audited is low. Zhao suggests again to split the material, 2-3 tons each time and ship them out separately. This way, Zhao notes, the amount is small and there is a low chance of inspection.
- Ex.26 -BSCMI1500006979
  - There were a total of 4 shipments for the 34,000 pounds of EMAI resin: (1) 8/21/11, (2) 5/16/12, (3) 7/11/12, and (4) 7/31/12.
- 5/16/12 2nd shipment: 5 tons of EMAI resin shipped by sea to Luxilon in Belgium (Ex. 27 - BSCM07700186099)
- 7/11/12 3rd Shipment: 5 tons of EMAI resin shipped by sea to Seattle, WA (Ex. 28 - BSCMI 1500006533)

- Shipment documents state to Chinese Customs that the resin was made in China by EMAI. Ex. 29 - BSCM13500000448
  - o Mullally (BSC) provided the information to clear the entry of the resin from China. Ex. 30 - BSCM13500000465
  - o BSC had to say it's made in China since it doesn't have original paperwork – if caught by customs – we will be in trouble. Ex. 15 BSCM12900000074

7/31/12 4th Shipment: 10,000lbs of EMAI resin shipped by sea to Seattle.

- Ex. 31 - 114 0001 at 0003
- Ex. 30 - BSCM1 1500004627

**617112** John Kummailil (Senior Manager, Corporate Engineer) from another BSC division told Charlie Smith and JP Delaney (with the Women's Health Division) he came across counterfeit material from EMAI.

- Ex. 32 - BSCM1 1500006904

**617/12** Kummailil told Charlie Smith that his BSC division did not run any tests to ensure the plastic EMAI attempted to sell BSC counterfeit, but Kummailil confirmed with the manufacturer that the lot number did not match and the hypothesis is that EMAI re-bagged "god knows what grade, or even recycled material, in bags that have the grade # they were looking for."

- Ex. 32 - BSCM1 1500006904

## Testing

(1) Testing does not matter because even perfect copy is still counterfeit

- Another BSC Corporate Engineer, John Kummailil did not perform testing on material he believed to be counterfeit. Confirmation of incorrect lot number was enough for Kummailil to conclude it was counterfeit. Ex. 32- BSCM1 1500006904

(2) BSC only tested one pellet from the first 4,000 pound purchase

- Cambridge report (Ex. 33 - BSCM07300068256)
- No pellets from the 3 separate shipments of 30,000lb purchase were tested.

(3) Wrong tests were performed.

- Ex. 34 - Marlex Data Sheet (previously Ex. 1)
- Cambridge report (Ex. 33 - BSCM07300068256)

(4) Chinese resin fails the tests

- Cambridge report (Ex. 33 - BSCM07300068256)

(5) Boston report omits findings from Cambridge report

- Ex. 35 - BSC Engineer report (BSCM1 1500005941) v. Cambridge Report (BSCM07300068256)

**D. Plaintiff's Motion for a Temporary Restraining Order and a Preliminary Injunction, and Plaintiff's Original Complaint**

None of the documents supporting Plaintiff's Motion for a Temporary Restraining Order and a Preliminary Injunction, and Plaintiff's Original Complaint, and none of the documents regarding alleged Marlex obtained from China have anything to do with anything that might legitimately qualify for a "confidential" designation under the Order and Rule 26, and that designation only serves to hide BSC's misconduct from the public. But the most important thing revealed by these supposedly "confidential" documents, in Plaintiff's view, is that BSC obtained degraded, untested, unlawful, and counterfeit material for use in its mesh products that likely pose an even greater risk than the products that landed BSC in this MDL in the first place. It is clear from BSC's records that its supply of true Phillips Marlex (actually manufactured and bought from the manufacturer, Phillips) ran out in approximately the third quarter of 2012. For Plaintiff and Class Members, it is almost certain they were implanted with this Chinese, counterfeit mesh. Worse, BSC claims to implant approximately 55,000 women a year with its mesh products-mesh made from Chinese resin passed off as "Marlex" without any supporting documentation or authenticity. Respectfully, perhaps a little perspective is in order. By the end of today, about 200 more women will have been unwittingly implanted with more of BSC's Chinese, counterfeit mesh. But none of them will know it. Plaintiff, Class Members, as well as their doctors, have an absolute right to know what, exactly, is being permanently implanted into their bodies. BSC should not, respectfully, be allowed to take that away from these women, too.

**E. Plaintiff's Challenge to BSC's "Confidential" Designation**

This is not just a run-of-the-mill discovery dispute. It's not just a tactic to leverage some secret settlement, then seal up all the records so no one else knows about it. Women's lives and health are at an even greater than expected risk as a result of BSC's use of substandard materials

in its mesh products, and, in Plaintiff's view, those concerns demand prompt exposure and action. Accordingly, Plaintiff filed this motion soon after broaching the subject with BSC's counsel. Plaintiff's counsel contacted BSC's lawyers by email on January 7, 2016, pointing out clear violation of the good faith provision of the Order through its wholesale use of the "confidential" designation of every single document.

### III. ARGUMENT AND AUTHORITIES

#### A. BSC's Burden

PTO #11 is a standard "umbrella" or "blanket" protective order issued pursuant to Fed. R. Civ. P. 26(c), and as such, the parties' compliance with PTO #11 is governed by Rule 26's "good cause" standard, with the burden clearly resting on the person making the challenged designation. *See In re Zyprexa Injunction*, 474 F. Supp. 2d 385, 416 (E.D.N.Y. 2007) ("[p]arties are permitted to challenge that designation [of confidentiality under an umbrella order] and the burden of establishing that there is good cause to protect the designated materials rests at all times with the party seeking protection"); *Parkway Gallery Furniture, Inc. v. Kittinger I Pennsylvania House Group, Inc.*, 121 F.R.D. 264, 267 (M.D.N.C. 1988) ("To the extent the parties wish to make motions to the Court and rely upon the designations of confidentiality, the Court requires the party who supports the confidentiality designation to prove the grounds for that position."); *see also* Order at II.B.4. ("the party claiming the designation of confidentiality or redaction has the burden of establishing that such confidential designation or redaction is proper").

[E]ven though a blanket protective order permits all documents to be designated as confidential, a party must agree to only invoke the designation in good faith. After receiving documents, the opposing party has the right to contest those documents which it believes not to be confidential. At this stage, the party seeking the protection shoulders the burden of proof in justifying retaining the confidentiality designation. Thus, the burden of proving confidentiality never shifts from the party asserting that claim -- only the burden of raising that issue.

*Parkway Gallery Furniture*, 121 F.R.D. at 268.

**B. Documents filed with the Court must be stripped of their "confidential" designation.**

Regardless of whether the Court rules that the wholesale declassification of BSC's supposedly "confidential" documents is appropriate, the Court should strip that classification from the documents filed with the Court in connection with Plaintiff's Motion for a Temporary Restraining Order and a Preliminary Injunction, and Plaintiff's Original Complaint, as well as the documents attached to this motion. "[W]hen documents are filed in support of any filing which the court actually considers, they constitute 'judicial documents' that would be subject to the common law right of access," and "such documents are judicial no matter how trivial the requested action is." *Washington v. Bruraker*, 2005 U.S. Dist. LEXIS 44958, \*22-23 (W.D. Va. Mar. 29, 2005).

"As a general rule, all documents filed for the Court's consideration in a civil case, even if not the subject of a judicial decision, are subject to presumptive access." *Walker Sys. v. Hubbell Inc.*, 188 F.R.D. 428, 429, 1999 U.S. Dist. LEXIS 15639, \*1-2 (S.D. W. Va. 1999); *see also Brown & Williamson Tobacco v. FTC*, 710 F.2d 1165 (6th Cir. 1983); *In re Coordinated Pretrial Proceedings in Petroleum Prods. Antitrust Litig.*, 101 F.R.D. 34, 38 (C.D.C.A. 1984). Furthermore, Rule 5(e) of the Federal Rules of Civil Procedure contemplates that the documents filed with the Court be publicly available. *See generally*, Fed. R. Civ. P., Rule 5(e); *Petroleum Prods.*, 101 F.R.D. at 38.

As discussed in *Minter*, "the common law presumes the right of the public to inspect and copy all judicial records, such as a motion filed with the court and exhibits thereto." *Minter*, 2010 U.S. Dist. LEXIS 136006 at \*47; *see also Rushford v. The New Yorker Magazine, Inc.*, 846 F.2d 249, 252 (4th Cir. 1988) (opining that "...discovery, which is ordinarily conducted in private, stands on a wholly different footing than does a motion filed by a party seeking action by

the court."). This presumption can be rebutted "if countervailing interests heavily outweigh the public interests in access." *Rushford*, 846 F.2d at 253.

And in addition to the common-law presumption, the public's First Amendment rights are implicated. In *Rushford* the Fourth Circuit held that the First Amendment public right of access standard, rather than the less rigorous common law standard, applies to documents filed with the trial court as attachments to a dispositive motion in a civil case. 846 F.2d at 253. Where the First Amendment provides a right of access, however, "denial must be necessitated by a compelling government interest and narrowly tailored to serve that interest." *Id.*; *Stone v. University of Md. Med. Sys. Co.*, 855 F.2d 178, 180 (4th Cir. 1988). While the Fourth Circuit does not appear to have addressed whether the First Amendment standard applies to documents submitted with a motion for an injunction, the Third Circuit has. And it does. *See Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1070 (3d Cir. 1984) (applying the First Amendment standard to a motion to seal and other motions regarding an ultimately unsuccessful motion for a preliminary injunction). District courts within the Fourth Circuit have reached the same conclusion. For instance, in *Allstate Ins. Co. v. Warns*, 2012 U.S. Dist. LEXIS 26174, \*49-50 (D. Md. Feb. 29, 2012), the court observed that for a successful motion for preliminary injunction of a final judgment, and expressed the belief that the more rigorous First Amendment standard for dispositive civil motions should apply to a motions to seal. *Id.* at \*49-50; Similarly, in *Bayer Cropscience Inc. v. Syngenta Crop Prat., LLC*, 2013 U.S. Dist. LEXIS 145933 (M.D.N.C. Oct. 9, 2013), the court "conclude[d] that the briefing and exhibits filed in connection with motions seeking injunctive relief are subject to the public's First Amendment right of access. *Id.* at \*6-6.

In this case, regardless of whether analyzed under the common law standard or the First Amendment, the documents filed with Motion for a Temporary Restraining Order and a Preliminary Injunction, and Plaintiff's Original Complaint are not legitimately "confidential" documents, and there is no basis for restricting public access to those documents. But even if there were, and even if BSC were able to demonstrate the required "compelling" interest necessary to satisfy the First Amendment (or the lesser burden under the common law test, if applicable), only those portions of the documents for which the compelling interest is demonstrated should be withheld. The Court "must ensure that the First Amendment protections are properly weighed and considered" and be "convinced that the documents have been only minimally redacted where absolutely necessary to protect against the disclosure of trade secret or other confidential information." *See In re C. R. Bard, Inc. Pelvic Repair System Prods. Liab. Litig.*, 2013 U.S. Dist. LEXIS 70189 at \*21 (S.D. W. Va. May 17, 2013). BSC already demonstrated it has neither the competence nor the desire to properly designate any of its documents as "confidential." Instead, BSC abused the process, as well as the privilege log and redaction authority, to thwart Plaintiff's efforts to ascertain the truth about this counterfeit resin implanted in Plaintiff and Class Members, and being implanted today in over 55,000 women per year. These women's right to know about the product being permanently implanted in their bodies is far more important than BSC's stock price. BSC lost sight of that fact years ago- Plaintiff prays this Court corrects such, reckless, corporate conceit. Release this information to the public. BSC certainly won't do it.

**C. The Court must weigh the importance of this information to public health and safety.**

Factors to consider when deciding if and how to limit disclosure include:

- (1) whether disclosure will violate any privacy interests;

- (2) whether the information is being sought for a legitimate purpose or for an improper purpose;
- (3) whether disclosure of the information will cause a party embarrassment;
- (4) whether confidentiality is being sought over information important to public health and safety;**
- (5) whether the sharing of information among litigants will promote fairness and efficiency;
- (6) whether a party benefiting from the order of confidentiality is a public entity or official; and
- (7) whether the case involves issues important to the public.

*In re C. R. Bard, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL No. 2187, 2014 U.S. Dist. LEXIS 57890, at \*2784-85 (S.D. W. Va. 2014) (emphasis added).

BSC cannot dispute that the documents improperly designated as "confidential" are important to public health and safety. They're all related to the origin of a medical device permanently implanted into women's bodies. These documents show that 200 women will be implanted today, tomorrow, and the day after that, with counterfeit, adulterated resin smuggled out of China by concealing it in different bags. These women, and their doctors, need to know the truth about the products BSC is implanting in them before they have them permanently implanted in their bodies, as well as deciding whether to risk removal if it's already too late.

#### IV. CONCLUSION AND PRAYER

For all the foregoing reasons, Plaintiff requests that the Court remove the "confidential" designation from all documents regarding the alleged Marlex BSC obtained from China, including, but not limited to, those documents submitted with Plaintiff's Original Complaint and Motion for a Temporary Restraining Order and a Preliminary Injunction and attached to this motion. Additionally, Plaintiff respectfully requests that any injunction hearing be open to the public. Finally, Plaintiff requests this Court shorten the time for Defendant Boston Scientific to respond to this motion and set a public, preliminary injunction hearing as soon possible where all these documents and testimony can be freely heard.

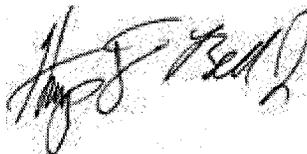
Dated January 19, 2016.

Respectfully Submitted,

THE MOSTYN LAW FIRM

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A handwritten signature in black ink, appearing to read "Harry F. Bell, Jr.", written in a cursive style.

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ATTORNEYS **FOR** PLAINTIFF

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing has been forwarded to all counsel of record on this 19th day of January, 2016, in accordance with the Federal Rules of Civil Procedure.

*J. Steve Mostyn* \_\_\_\_\_  
J. Steve Mostyn



**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

TERESA L. STEVENS,  
Plaintiff

v.

CIVIL ACTION NO. 2:16-cv-0265

BOSTON SCIENTIFIC CORPORATION, EMAi  
PLASTIC RAW MATERIAL CO, LTD.,  
PROXY BIOMEDICAL LIMITED, AND  
LUXILON INDUSTRIES NV,  
Defendants.

**ORDER GRANTING AMENDED MOTION TO REMOVE ANY "CONFIDENTIAL "  
DESIGNATION FROM DOCUMENTS**

Before the Court is the *Motion to Remove Any "Confidential" Designation From Documents* filed by the Plaintiff. Having duly considered the motion and any response thereto, the Court is of the opinion that the motion should be granted. The Court finds that Defendant Boston Scientific Corporation indiscriminately marked documents cited by Plaintiff in support of her Plaintiffs' Class Action Complaint and Motion for a Temporary Restraining Order and a Preliminary Injunction as "confidential" in violation of the "good faith" requirement set out in ¶ 4 of the Stipulated Protective Order, Pretrial Order # 11 ("PTO #11"). PTO #11 allows a party to designate material as "confidential" only if the producing party believes in good faith that the material constitutes or discloses information that qualifies for protection pursuant to Fed. R. Civ. P. 26(c). Defendant Boston Scientific Corporation has abused PTO #11 entered into in these cases through the indiscriminate designation of apparently every document they have produced as either "confidential" or "highly confidential." No good cause exists under PTO #11 and Rule 26 for Defendant's mass designation all discovery documents as "confidential" or "highly confidential." The information being sought is important to public health and safety. The First

Amendment right of public access applies to these documents and no compelling governmental interest exists to overcome that right.

It is therefore ORDERED that the "confidential" designations placed on all documents regarding the alleged Marlex BSC obtained from China, including, but not limited to, those documents submitted with Plaintiff s Original Complaint and Motion for a Temporary Restraining Order and a Preliminary Injunction and attached to Plaintiff s motion, may be disregarded, and Plaintiff is released from any and all restrictions on the use or disclosure of materials marked "confidential" by Defendant Boston Scientific Corporation, as well as any obligation to return or destroy such materials at the conclusion of litigation.

Finally, the injunction hearing shall not be sealed and is open to the public.

Signed this \_\_\_ day of \_\_\_\_\_, 2016.

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United States District Judge